

10/517626

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
(National Phase of International App.: PCT/US03/18202, WO 03/103604 A2)**

In re the  
application of: **Gian Luca Araldi, et al.**

International Application No.: **PCT/US03/18202**

International Filing Date: **June 9, 2003**

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For: **GAMMA LACTAMS AS PROSTAGLANDIN  
AGONISTS AND USE THEREOF**

Attorney Docket No.: **SNI-003US**

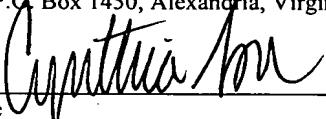
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**INFORMATION DISCLOSURE STATEMENT**

Dear Sir:

Applicants and their Attorney are aware of the following publications and information, listed on the attached PTO Form SB/08, and in accordance with 37 CFR §1.97 hereby submit these publications for the Examiner's consideration. Reference ID No. A10 was cited in an International Search Report mailed December 10, 2003 during the prosecution of PCT/US03/18202 which corresponds to the above referenced application. A copy of the report and each cited publication is enclosed. Furthermore, in accordance with

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37 CFR §1.704(d), Applicants note that this communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of this statement.

This statement is not to be interpreted as a representation that the cited publications are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any publication herein be construed *per se* as a representation that such publication is prior art. Moreover, Applicants understand that the Examiner will make an independent evaluation of the cited publications.

In accordance with 37 CFR §1.97(b)(1), no additional costs are believed to be due in connection with the filing of this Information Disclosure Statement. However, please charge any necessary fees in connection with the enclosed statement to our Deposit Order Account No. 12-0080.

Respectfully submitted,  
LAHIVE & COCKFIELD, LLP



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Date: 10 December 2004

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Substitute for form 1449A/B/PTO

**Complete if Known**

Application Number	Not Yet Assigned
Filing Date	Herewith
First Named Inventor	Gian Luca Araldi
Art Unit	N/A
Examiner Name	Not Yet Assigned

**INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

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of

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**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
A1	3,873,566		03-25-1975	Scribner	
A2	4,003,911		01-18-1977	Scribner	
A3	4,033,989		07-05-1977	Bundy	
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A10	US2002/0065308 A1		05-30-2002	Cameron, et al.	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
A11	WO 96/03380 A1		02-08-1996	Zeneca Limited		
A12	WO 96/06822 A1		03-07-1996	Zeneca Limited		
A13	EP 0 752 421 A1		01-08-1997	Zeneca Limited		
A14	WO 97/00863 A1		01-09-1997	Zeneca Limited		
A15	WO 97/00864 A1		01-09-1997	Zeneca Limited		
A16	EP 1 110 949 A1		06-27-2001	Pfizer Products Inc.		
A17	WO 02/24647 A1		03-28-2002	Ono Pharmaceutical Co., Ltd.		
A18	WO 03/007941 A1		01-30-2003	F.Hoffmann -La Roche AG		
A19	WO 03/009872 A1		05-12-2004	Ono Pharmaceutical Co., Ltd.		

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**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
A20		Abramovitz, et al. "The utilization of recombinant prostanoid receptors to determine the affinities and selectivities of prostaglandins and related analogs." Biochim Biophys Acta. 2000 Jan 17;1483(2):285-93.	
A21		Bennett, et al. "Synthesis and biological activity of a series of 1-aryl-3-pyrazolidinones." J Med Chem. 1976 May;19(5):715-7.	
A22		Boie, et al. "Molecular cloning and characterization of the four rat prostaglandin E <sub>2</sub> prostanoid receptor subtypes." Eur J Pharmacol. 1997 Dec 11;340(2-3):227-41.	
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				Art Unit	N/A
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Sheet	2	of	2	Attorney Docket Number	SNI-003US

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Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			
	B1	Coleman, et al. "International Union of Pharmacology classification of prostanoid receptors: properties, distribution, and structure of the receptors and their subtypes." <i>Pharmacol Rev.</i> 1994 Jun;46(2):205-29.			T <sup>2</sup>
	B2	Corey, et al. "A stable and easily prepared catalyst for the enantioselective reduction of ketones. Applications to Multistep Systheses." <i>J. Am. Chem. Soc.</i> 1987. 109:7925-26.			
	B3	Fleisch, et al. "LY171883, 1-< 2-hydroxy-3-propyl-4-< 4-(1H-tetrazol-5-yl) butoxy > phenyl > ethanone, an orally active leukotriene D4 antagonist." <i>J Pharmacol Exp Ther.</i> 1985 Apr;233(1):148-57.			
	B4	Gardiner, PJ. "Characterization of prostanoid relaxant/inhibitory receptors (psi) using a highly selective agonist, TR4979." <i>Br J Pharmacol.</i> 1986 Jan;87(1):45-56.			
	B5	Hundertmark, et al. "Pd(PhCN)( <sub>2</sub> )Cl( <sub>2</sub> )/P(t-Bu)( <sub>3</sub> ): a versatile catalyst for Sonogashira reactions of aryl bromides at room temperature." <i>Org Lett.</i> 2000 Jun 15;2(12):1729-31.			
	B6	Ichikawa, et al. "Molecular aspects of the structures and functions of the prostaglandin E receptors." <i>J Lipid Mediat Cell Signal.</i> 1996 Sep;14(1-3):83-7.			
	B7	Langlois, et al. "Intramolecular Mitsunobu reaction in the region- and stereoselective synthesis of cis-4,5-disubstituted piperidin-2-ones." <i>Tetrahedron Letters.</i> 2000 41:8285-8288.			
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	B9	Mikolajczyk, et al. "Synthesis of ( $\pm$ )-Rosaprostol." <i>J. Org. Chem.</i> 1998. 63:8894-8897.			
	B10	Minami, et al. "Characterization of EP-receptor subtypes involved in allodynia and hyperalgesia induced by intrathecal administration of prostaglandin E2 to mice." <i>Br J Pharmacol.</i> 1994 Jul;112(3):735-40.			
	B11	Nair, et al. "Folate analogues. 31. Synthesis of the reduced derivatives of 11-deazahomofolic acid, 10-methyl-11-deazahomofolic acid, and their evaluation as inhibitors of glycinamide ribonucleotide formyltransferase." <i>J Med Chem.</i> 1989 Jun;32(6):1277-83.			
	B12	Okuma, et al. "An Efficient Synthesis of (R)-(+) -Recifeiolide and Related Macrolides by Using Enantiomerically Pure (R)- (-)-5-Methyl-2,2,2-triphenyl-1,2A <sup>5</sup> -oxaphospholane." <i>Tetrahedron.</i> 1998. 54:4243-50.			
	B13	Tani, et al. "Synthesis of a Highly Selective EP2-Receptor Agonist." <i>Synlett.</i> 2002, pp. 239-242.			
	B14	Thivierge, et al. "Prostaglandin E2 induces resistance to human immunodeficiency virus-1 infection in monocyte-derived macrophages: downregulation of CCR5 expression by cyclic adenosine monophosphate." <i>Blood.</i> 1998 Jul 1;92(1):40-5.			
	B15	Ushikubi, et al. "Roles of prostanoids revealed from studies using mice lacking specific prostanoid receptors." <i>Jpn J Pharmacol.</i> 2000 Aug;83(4):279-85.			
	B16	Wilkinson, et al. "Diethylanilineborane: A Practical, safe, and consistent-quality borane source for the large-scale enantioselective reduction of a ketone intermediate in the synthesis of (R,R)-Formoterol." <i>Organic Process Research &amp; Development.</i> 2002 6:146-8.			

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